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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	08/909,130	Confirmation No.: 1242
Applicant	: Cox, et al.	
Filed	: August 11, 1997	
TC/A.U.	: 3763	
Examiner	: DeSanto, Matthew F.	
Docket No.	: 1001.1138103	
Customer No.	: 28075	

TRANSMITTAL SHEET

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Assistant Commissioner for Patents
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By Lynn Thompson
Lynn Thompson

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APPEAL BRIEF IN ACCORDANCE WITH 37 C.F.R. §1.192

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By Lynn Thompson
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Dear Sir:

Pursuant to 37 C.F.R. § 1.192 this appeal brief is being timely submitted within two months from the date of the notice of appeal of January 29, 2004 in triplicate and accompanied by the fee set forth in 37 C.F.R. § 1.17(c).

The brief contains the following items under appropriate headings in the order required by the regulations on the following page numbers.

Real Party in Interest is found on page 3 of this paper.

Related Appeals and Interferences is found on page 3 of this paper.

Status of Claims is found on page 3 of this paper.

Status of Amendments is found on page 3 of this paper.

Real Party in Interest

The real party in interest is the assignee of record, Scimed Life Systems, Inc.

Related Appeals and Interferences

Neither appellant, appellant's legal representatives, or assignee know of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of the Claims

Claims 4, 5, and 10-12 have been rejected and are appealed. Claims 1-3 and 6-9 have been cancelled.

Status of Amendments

No amendments were filed subsequent to final rejection.

Summary of Invention

The invention pertains to a balloon angioplasty catheter having a perfusion lumen extending through the balloon to provide blood flow through the balloon when it is inflated. Pg. 4, l. 25 through pg. 5, l. 5.

One embodiment corresponding to the invention of claim 4 may be understood with reference to Figure 1 and the detailed description beginning at line 16 of page 12. A balloon angioplasty catheter comprises an elongated catheter body (partially shown in Figure 1) having a proximal end (not shown) and a distal end (item 11). See pg. 12, ll.

18-20. A balloon 10 includes an inflatable envelope portion 16 and has a proximal end (at the proximal end of waist 18) and distal end (at the distal end of waist 19). Pg. 13, ll. 11-12 & 20-23. A perfusion lumen 17 extends through the balloon, the perfusion lumen having a proximal end and a distal end (in Figure 1, the proximal end may be seen at the blood flow inlet 33 and the distal end is near lumens 26 and 27), the proximal end of the perfusion lumen being proximate the proximal end of the balloon, the perfusion lumen decreasing in cross section within the inflatable envelope portion (as can be seen in Figure 1).

One embodiment corresponding to the invention of claim 10 may be understood with reference to Figure 27 and the detailed description beginning at line 14 of page 21. This is essentially a modification of a previously described embodiment and so the discussion will be limited to the elements not already described. A balloon angioplasty catheter comprises an elongate catheter body, a balloon, a perfusion lumen extending through the balloon, the perfusion lumen having a distal end and a proximal end. This has been described above. The balloon angioplasty catheter also comprises a guidewire lumen, the guidewire lumen being disposed through the perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire. See pg. 21, ll. 17-22.

Issues

1. Whether claims 4 and 5 are patentable under 35 U.S.C. § 102(b) over Saab (U.S. Patent No. 4,820,349).

2. Whether claim 10 is patentable under 35 U.S.C. § 102(b) over Sahota (U.S. Patent No. 5,090,958).

3. Whether claims 4, 5 and 10-12 are patentable under 35 U.S.C. § 103(a) over Sahota in view of Saab.

Grouping of Claims

In the third issue, claims 4 and 5 do not stand and fall with claims 10-12 for the purposes of this brief. Claim 4 is an independent claim directed towards a first invention and claim 10 is an independent claim directed towards a second invention having certain elements which are distinct from the invention of claim 4. While both claims were rejected under 35 U.S.C. § 103(a) as unpatentable over Sahota in view of Saab, the argument below for patentability and against the rejection relies on different theories and different elements of the case for prima facie obviousness are challenged. Applicants therefore submit that it is appropriate to consider these two sets of claims separately.

Argument

35 U.S.C. § 102(b) rejection of claims 4 and 5 over Saab.

The first issue is whether claims 4 and 5 are patentable under 35 U.S.C. § 102(b) over Saab (U.S. Patent No. 4,820,349). Applicants submit that the elements of claim 4 are not taught or suggested by Saab, and that the examiner erred in his interpretation of the term 'proximal' and in his analysis depending on his errant interpretation.

Specifically, Saab does not disclose a perfusion lumen extending through the balloon, the perfusion lumen having a proximal and a distal end, *the proximal end of the perfusion lumen being proximate the proximal end of the balloon*, the perfusion lumen decreasing distally in cross section within the inflatable envelope portion. As one can see from Figure 2 of Saab, the only lumen extending through the balloon is main lumen 18. Main lumen 18 is through the length of shaft 12. Col. 4, ll. 35-41. Therefore the proximal end of the main lumen can terminate no closer to the proximal end of shaft 12, which ends at bifurcated fitting 30. Col. 5, ll. 17-18. The proximal end of this shaft and consequently the proximal end of the lumen is not proximate the proximal end of the balloon.

I. The examiner incorrectly confuses 'proximal' and 'proximate'.

The examiner maintains the rejection based on a confusion of the terms 'proximate' and 'proximal'. See page 2 of the office action mailed November 18, 2003. The examiner treats 'proximal' as meaning 'proximate'. While 'proximal' may mean 'proximate' in certain contexts, this meaning of 'proximate' cannot be supported by a reasonable reading of either Saab or the applicant's own specification. Large parts of the specifications and claims of Saab and the present application make no sense if 'proximal' is read as 'proximate' and therefore an alternate definition must be the one intended.

Two definitions are given for 'proximal': 1) nearest; proximate and 2) nearer to a point of reference such as an origin, a point of attachment, or the midline of the body. See http://dictionary.reference.com/search?q=proximal.

The present application uses 'proximal' exclusively in the second sense (i.e. "nearer to a point of reference such as an origin, a point of attachment, or the midline of

the body"). Saab (the art cited against claim 4 and 5) uses 'proximal' exclusively in the second sense. Other patents in this art area also appear to use 'proximal' exclusively in the second sense; no contrary examples were found.

Review of the application, the cited art and other patents in the art area reveals that the term 'distal' is often used in conjunction with the term 'proximal'. 'Distal' is given two definitions at Dictionary.com: 1) anatomically located far from a point of reference, such as an origin or a point of attachment, and 2) situated farthest from the middle and front of the jaw, as a tooth or tooth surface. See http://dictionary.reference.com/search?r=2&q=distal. Because jaws and teeth are not mentioned in the art area, the meaning "situated farthest from the middle and front of the jaw, as a tooth or tooth surface" can be eliminated. The definition "anatomically located far from a point of reference, such as an origin or a point of attachment" is parallel and complimentary to the second definition of proximal; indeed 'proximal' and 'distal' are used as opposites in the art area. It would be illogical if 'distal' means "anatomically located far from a point of reference, such as an origin or a point of attachment" while 'proximal' means "nearest, proximate" rather than "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body".

II. The present application uses 'proximal' to mean "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body".

As mentioned above, the present application uses 'proximal' exclusively in the second sense. "One embodiment of the invention allows for a smaller balloon catheter cross section by having the perfusion lumen *proximal* end be of large cross section, decreasing to a smaller cross section at the *distal* end." Pg. 7, ll. 9-12. "A perfusion

lumen 17 extends through the interior of the balloon envelope 16 from a proximal balloon waist 18 to a distal balloon waist 19." Pg. 13, ll. 12-15. Figure 1, which depicts a partial cut-away of a distal portion of an embodiment of the invention (see pg. 12, ll. 16-20), shows proximal waist 18 to be proximal the balloon envelope 16, and distal waist 19 to be distal the balloon envelope 16. The figure also shows that the proximal end of perfusion lumen 17 has a larger cross section that the distal end. Applicants will not cite every instance of 'proximal' in the application, but will say that in every instance it is clear that 'proximal' means "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body". If the board has any doubt about this, applicants encourage the board to review the application in detail.

III. The cited prior art uses 'proximal' to mean "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body".

The art cited against claims 4 and 5, Saab, uses 'proximal' exclusively to mean "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body". For example: "The inflation lumen terminates at the juncture of the proximal and distal segments of the shaft." Saab, col. 2, ll. 35-37. If 'proximal' means "nearest", one is left confused because the sentence does not indicate what the nearest segment of the shaft is nearest to. In contrast, if 'proximal' means "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body", the sentence makes sense. The proximal segment of the shaft is the segment of the shaft nearer to a point of reference such as the origin. Therefore, the meaning of proximal as "nearest; proximate" cannot apply. Saab divides many components using the terms 'proximal' and 'distal'. The balloon dilation catheter at col. 4, ll. 30-32, the shaft at col. 4, ll. 35-37, the sleeve at

col. 4, ll. 49-50 and 54 are all examples found in the *first column* of the detailed description. Applicants have reviewed Saab and can find no instance where 'proximal' means or can mean "nearest; proximate".

IV. The prior art in the art area uses 'proximal' to mean "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body".

As previously mentioned to the examiner, this use of 'proximal' and 'distal' is notoriously well known in the art area. A search of the patent database for patents containing the terms 'proximal', 'distal' and also 'guidewire' or 'catheter' reveals over 16,000 such patents. All the patents that applicants have reviewed use 'proximal' to mean "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body". For example, U.S. Patent No. 6,711,440 to Deal, et al. describes in the abstract "a photonic catheter containing optical conductors conducting light energy in two directions between electronics at a catheter *proximal* end and electrical stimulation and sensing components at a catheter *distal* end". U.S. Patent No. 6,749,465 to Mitchell, et al. recites in claim 25 "a filament secured to a *distal* region of the flexible elongate body and extending to a *proximal* region of the flexible elongate body, wherein *proximal* displacement of the filament transitions the device to the expanded state". U.S. Patent 6,711,443 to Osypka recites in claim 1 "a first elongated lead body having opposed *proximal* and *distal* end portions". Reference to these documents makes clear, if the above passages do not, that 'proximal' is in every instance used to mean "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body" and not "nearest, proximate". Applicants have not reviewed all 16,000 plus patents returned by the search, but of those reviewed, none used proximal to mean "nearest,

proximate". Applicants suspect that they would be hard pressed to obtain a patent in this art area which used 'proximal' in that sense. This indicates two things. First that 'proximal' means "nearer to a point of reference such as an origin, a point of attachment, or the midline of the body" and second that those of skill in the art would so interpret 'proximal'.

When the proper interpretation is given to 'proximal', one can readily see that Saab does not anticipate claim 4. Claim 4 requires that the proximal end of the perfusion lumen is proximate the proximal end of the balloon. The main lumen of Saab does not end proximally until the proximal-most end of luer connector 36. See Figure 1 and col. 5, ll. 17-25. Thus the proximal end of the lumen is not proximate the proximal end of the balloon. There is no anticipation. Nor is there any danger of applicants claiming previously disclosed matter. Saab provides a catheter where a dye or radiopaque agent may be injected through the main lumen to a region distal the balloon. The invention of claim 4 provides a catheter where blood can circulate through the treated region, for example by permitting blood flow into the proximal end of the perfusion lumen and out the distal end of the perfusion lumen, even while the balloon is inflated. The catheter of Saab does not provide this function nor does it disclose structure which may do so. Applicants therefore submit that claim 4 is novel over Saab and is consequently in condition for allowance. Claim 5, depending from claim 4 and containing additional elements, is also in condition for allowance.

The examiner relied on an objectively unreasonable interpretation of 'proximal' when rejecting claims 4 and 5. When 'proximal' is interpreted correctly and in the only reasonable manner, Saab does not disclose the perfusion lumen having a proximal end

proximate the proximal end of the balloon. Applicants therefore request that the board rule in favor of the applicants on this issue.

35 U.S.C. § 102(b) rejection of claim 10 over Sahota.

Similarly, claim 10 is patentable under 35 U.S.C. § 102(b) over Sahota (U.S. Patent No. 5,090,958). Sahota does not disclose every element of claim 10. The examiner erred in not giving due patentable weight to the phrase "being collapsible, during normal use".

The key element of claim 10 for the purpose of this discussion is the last: "a guidewire lumen, the guidewire lumen being disposed through the perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire."

The examiner notes that the term 'collapsible' is a functional language statement and that every lumen is collapsible when enough push is exerted on the catheter. See the office action of November 18, 2003, pg 2, lines 4-7. This analysis fails in two respects. First, the claim does not merely recite "collapsible", it recites "collapsible, during normal use". The examiner fails to give the phrase "during normal use" any weight. Second, the examiner fails to show where Sahota discloses a guidewire lumen collapsible during normal use.

Everything is collapsible when enough push is exerted. By this logic, we travel to work in collapsible vehicles, work in collapsible buildings and we ourselves are collapsible. This interpretation completely eviscerates the term 'collapsible' of any meaning whatsoever. "Collapsible" in the claim would have a more definite meaning then the one given it by the examiner even without the phrase "during normal use".

Fortunately, the modification of "collapsible" by "during normal use" makes the interpretation of the claim easier still. The normal use of a balloon angioplasty catheter such as the one claimed in claim 10 is as follows. The balloon angioplasty catheter is percutaneously inserted into the vascular of a patient. The catheter may be advance over a guidewire or through a guidecatheter to an area to be treated. When the balloon reaches the area of interest, it is inflated to treat the region. Generally this is done to reduce an occlusion or blockage in a blood vessel. Great effort is made in the design of these catheters and guidewires to reduce unwanted trauma to the blood vessels, which even when healthy are delicate and easily bruised, punctured or torn. The surfaces of these devices are often lubricious and the distal ends often soft or even floppy. As can be readily seen, during normal use the level of force which can be exerted on a catheter is quite limited. Any force that damages the vasculature is generally abnormal. Thus, while every lumen may be collapsible when enough push is exerted on it, not every lumen is collapsible during normal use.

Figure 10 of Sahota shows a guidewire lumen disposed in a perfusion lumen extending through the balloon. However, Sahota does not disclose, by word or drawing, that the guidewire lumen is collapsible during normal use. Unlike Sahota, the invention of claim 10, by having a guidewire lumen that is collapsible, during normal use, in the absence of an inserted guidewire permits an increase in the cross sectional area available to the perfusion lumen. Consequently, the blood flow through the perfusion lumen may be increased.

Applicants submit that claim 10 is patentable over Sahota because Sahota does not disclose each element of the claim, specifically the guidewire lumen that is

collapsible during normal use. As the examiner's rejection was based on a claim interpretation which did not give reasonable weight to all the elements of the claim, applicants requests the board to rule in applicants' favor on this issue.

35 U.S.C. § 103(a) rejection of claims 4, 5 and 10-12 over Sahota in view of Saab.

Claims 4, 5 and 10-12 are patentable under 35 U.S.C. § 103(a) over Sahota in view of Saab. This rejection is based in large part on the errors discussed in detail above. Applicants submit that the examiner erred in asserting this rejection because certain elements are disclosed by neither reference nor is there any suggestion or teaching to modify either reference to produce the missing elements.

Claim 4 is nonobvious over Sahota in view of Saab. The examiner suggests modifying Sahota by modifying the guidewire lumen to have the smaller distal cross section of Saab. A prima facie case of obviousness has not been made because the modification may render the catheter of Sahota unsuitable for its intended purpose. One of the purposes of the catheter of Figures 8-10 is to act as a shunt if the angioplasty operation is unsuccessful. Col. 7, lines 29-31. If the operation is unsuccessful, the vessel wall may collapse and the stenosis will still be present. Thus distal perfusion ports 56 may be blocked by the stenosis or a collapsed vessel wall. This then leaves only the distal end opening of bypass lumen 68 for perfusion. If the bypass lumen is modified so that the perfusion lumen decreases distally in cross section within the inflatable envelope portion, the cross-sectional area of this distal opening will decrease dramatically. This smaller opening may render the catheter of Sahota unsuitable to use as a shunt. Sahota notes that a small amount of blood flow is not usually sufficient to prevent infarction.

Col. 7, ll. 20-24. The catheter of Saab is not limited by this consideration. The perfusion lumen of Saab is not intended to permit blood flow to continue during an angioplasty operation, rather the perfusion lumen is intended to be used to inject radiopaque dye distal of the balloon. As the dye is under an external, positive pressure source, blockage of the perfusion lumens is not an issue. As no prima facie case of obviousness has been made, applicants submit that claim 4 is patentable over Sahota in view of Saab. As claim 5 depends from claim 4 and contains additional elements, applicants submit that this claim is in condition for allowance as well. Applicants therefore request that the board rule in favor of the applicants on this issue.

Claim 10 is also nonobvious over Sahota in view of Saab. No prima facie case of obviousness has been made against this claim because neither reference discloses each and every claim element.

As discussed above with reference to the second issue, Sahota does not disclose a guidewire lumen that collapses during normal use. As can be seen from an examination of the reference, Saab does not disclose such a lumen either. Saab discloses an inflation lumen that collapses around the guidewire lumen if a vacuum is applied to the inflation lumen. Indeed, in one embodiment the guidewire lumen is reinforced with a coil to reduce the chance of collapse when the balloon is inflated. Col. 4, ll. 63-68. As neither reference discloses a guidewire lumen that is collapsible under normal use, applicants submit that claim 10 is in condition for allowance. As claims 11-12 depend from claim 10 and contain additional elements, applicants submit that these claims are in condition for allowance as well. Applicants therefore request that the board rule in favor of the applicants on this issue.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Cox, et al.

By their Attorney,

Date: March 24, 2004

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Appendix

The following is a listing of the claims, including those involved in the appeal.

1 –3 (Cancelled)

4. (Previously Amended) A balloon angioplasty catheter comprising:

an elongated catheter body having a proximal end and a distal end;

a balloon including an inflatable envelope portion, the balloon having a proximal end and a distal end;

a perfusion lumen extending through the balloon, the perfusion lumen having a proximal end and a distal end, the proximal end of the perfusion lumen being proximate the proximal end of the balloon, the perfusion lumen decreasing distally in cross section within the inflatable envelope portion

5. (Original) A balloon angioplasty catheter as recited in claim 4 , wherein the perfusion lumen includes a metallic ribbon coil support.

6 – 9 (Cancelled)

10. (Previously Amended) A balloon angioplasty catheter comprising :

an elongated catheter body;

a balloon;

a perfusion lumen extending through the balloon, the perfusion lumen having a distal end and a proximal end;

a guidewire lumen, the guidewire lumen being disposed through the perfusion lumen and being collapsible, during normal use, in the absence of an inserted guidewire.

11. (Original) A balloon angioplasty catheter as recited in claim 10, wherein the perfusion lumen includes a metallic ribbon coil support.

12. (Original) A balloon angioplasty catheter as recited in claim 10, wherein the perfusion lumen distal end has a smaller cross section than the perfusion lumen proximal end.